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10/584,179	04/17/2007	Vincent Peter Crabtree	884B.0003.U1(US)	4741
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HARRINGTON & SMITH 4 RESEARCH DRIVE, Suite 202 SHELTON, CT 06484-6212			EXAMINER MESSERSMITH, ERIC	
			ART UNIT 3735	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,179	Applicant(s) CRABTREE ET AL.	
	Examiner Eric Messersmith	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/23/2006, 02/02/2007, 03/19/2010</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Invocation of 35 USC § 112, Sixth Paragraph

Examiner acknowledges Applicants' invocation of Section 112, Sixth Paragraph for claims 1-10 and 17-26. Examiner will therefore construe these claims to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Claim Objections

Claim 1 is objected to because of the following informalities: There are several instances in claim 1 where the definite article (e.g., "the") is used without a corresponding indefinite article (e.g., "a" or "an"). For instance, "the arterial blood volume" should be "an arterial blood volume," and "the ratio" should be "a ratio." Examiner understands Applicants' intent, but these changes should be made so that each claim defines its proper scope. Other claims have similar language. Appropriate correction is required.

Claim 30 is objected to because of the following informalities: There should be an "and" between the first and second clauses in claim

Claim 35 is objected to because of the following informalities: It appears as though Applicant intended to make this claim a method claim. Therefore, "A system" should be changed to "A method." Further, a semicolon should be added after the second clause.

Claim Rejections - 35 USC § 101

Regarding claims 11-16 and 27-29 and 35, method claims must have a specialized and limited meaning to qualify as a patent-eligible process claim. The test for a method claim is whether the claimed method is tied to a particular machine or apparatus or transforms a particular article into a different state or thing. The machine or transformation must impose meaningful limits on the method claim's scope to pass the test. This means an applicant must recite a specific machine or a particular transformation of a specific article or composition of matter in an insignificant step is not sufficient to pass the test. As applicant's claims fail to recite a specific apparatus in carrying out any of the aforementioned method steps, they fail to be patent-eligible processes.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 19-20 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 3, it is unclear whether "the signal" recited in this claim refers to the signal corresponding to the first posture, the second posture, or both.

As to claims 19-22, the limitation "the indicator" is recited in the first line of each claim. There is insufficient antecedent basis for this limitation in the claim. It is unclear

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whether "the indicator" is "a quantitative indicator" recited in claim 17 or some other indicator.

As claims 27-29, claim 27 recites the limitation "means for calculating" in line 7 of the claim. There is insufficient antecedent basis for this limitation in the claim. Because it is in a method claim, however, the "means for calculating" is understood to mean "calculating."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by an article entitled "Influence of different types of recovery positions on perfusion indices of the forearm" by Rathgeber et al (hereinafter "Rathgeber").

As to claim 11, Rathgeber discloses detecting a signal dependent upon the arterial blood volume in a limb of the subject when the subject is in a first posture (see section 2.2 on pp 14-15); detecting the signal dependent upon the arterial blood volume in the limb of the subject when the subject is in a second posture, different to the first posture (see section 2.2 on pp 14-15); and calculating a quantitative indicator that is dependent upon the ratio of the signal for the first posture to the signal for the second posture (see p 15 – $(PPI)=(AC/DC)$ and Fig 6 and accompanying text).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 12-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over an article entitled "Influence of different types of recovery positions on perfusion indices of the forearm" by Rathgeber et al (hereinafter "Rathgeber") in view of US 2003/0163033 A1 (Dekker).

As to claim 1, Rathgeber discloses detection means for detecting a signal dependent upon the arterial blood volume in a limb of the subject when the subject is in a first posture and also when the subject is in a second posture, different to the first posture (see section 2.2 on pp 14-15). Rathgeber discloses a formula for calculating a quantitative indicator that is dependent upon the ratio of the signal for the first posture to the signal for the second posture (see p 15 – $(PPI)=(AC/DC)$ and Fig 6 and accompanying text), but does not explicitly disclose the processing means for calculating it). Dekker discloses processing means capable of calculating a quantitative indicator that is dependent upon the ratio of the signal for the first and second posture (see para [0019], [0041] and [0052]) and means for separating the parameter into a first component and a second component (para [0021] to [0022]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine

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the means for detecting an arterial-blood-volume-dependent signal disclosed by Rathgeber with the processing means and separating means disclosed by Dekker to automate the calculation disclosed by Rathgeber.

As to claims 2, Rathgeber further teaches that the quantitative indicator (PPI) is directly proportional to the ratio of the signal for the first posture to the signal for the second posture (see p 15 – $(PPI) = (AC/DC)$ and Fig 6 and accompanying text).

As to claim 3, Rathgeber further teaches that the signal is a pulsating component of a measured parameter (AC), the measured parameter being dependent upon the blood volume in the subject's limb (see Fig 5).

As to claim 4, Rathgeber further teaches that the calculation of the quantitative indicator is additionally dependent upon the ratio of a non-pulsating component of the measured parameter for the second posture to a non- pulsating component of the measured parameter for the first posture (see Fig 6 and accompanying text – PPI change as percentage of supine in various positions).

As to claim 5, Rathgeber further teaches that the quantitative indicator is directly proportional to the ratio of the non-pulsating component of the measured parameter for the second posture to the non-pulsating component of the measured parameter for the first posture (see Fig 6 and accompanying text – PPI change as percentage of supine in various positions).

As to claim 6, Rathgeber discloses measurement means operable to measure a parameter indicative of the blood volume of the subject's limb when the subject is in a first posture and to measure the parameter when the subject is in a second posture and

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comprising means for isolating a pulsating component of the measured parameter (a pulse oximeter is capable of measuring a parameter indicative of blood volume).

As to claims 7, 14 and 31, Rathgeber does not disclose wherein the limb is a foot. Rathgeber does disclose the limb being a hand (p 15, right column, line 4-5). Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, the finger pulse oximeter is capable of performing the intended use.

As to claims 8-9, 15-16, 25-26 and 32, Rathgeber further teaches wherein the position of the limb is changed between the first posture and the second posture, a portion of the limb in the first posture being at a first elevation and a portion of the limb in the second position being at a second position (Fig 1-4, 6 and accompanying text)..

As to claim 10, 23 and 33-34, Rathgeber discloses the measured parameter being measured by pulse oximetry (which inherently is of fixed intensity) and the ratio of the signal for the first posture to the signal for the second posture reduces subject dependent influences such as variable light absorption of the blood and tissue in the limb for different subjects (p 15, right column, line 4-5 –ratio of the signals in the first and second postures inherently meets this intended use).but is silent as to whether measurement is the intensity of light reflected from the limb. Dekker teaches that pulse oximeters are either reflectance or transmittance types (para [0003]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

to try a pulse oximeter that measures the intensity of light reflected from the limb, since there are only a finite number of solutions possible.

Regarding claims 12-13, Rathgeber discloses the step of measuring a parameter that is dependent upon the blood volume in the subject's limb and further discloses wherein the quantitative indicator is additionally dependent upon the ratio of the non-pulsating component of the measured parameter for the second posture to the non-pulsating component of the measured parameter for the first posture. (see section 2.2 on pp 14-15) but does not specifically disclose the step of isolating, as the signal, a pulsating or non-pulsating component of the measured parameter. Dekker discloses the step of isolating, as the signal, a pulsating and non-pulsating components of the measured parameter (para [0018]-[0019], [0022]). It would have been obvious to one of ordinary skill in art at the time the invention was made to combine the steps disclosed by Rathgeber with the signal isolating step disclosed by Dekker, since isolating the pulsating and/or non-pulsating components allows arterial and/or venous flow and oxygen saturation to be independently monitored.

As to claim 17, Rathgeber discloses measurement means for measuring a parameter dependent upon the arterial blood volume in a limb of the subject when the subject is in a first posture and also when the subject is in a second posture, different to the first posture (see section 2.2 on pp 14-15). Rathgeber discloses a formula for calculating a quantitative indicator that is dependent upon the ratio of the signal for the first posture to the signal for the second posture (see p 15 – $(PPI) = (AC/DC)$ and Fig 6 and accompanying text), but does not explicitly disclose the means for separating the

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parameter into a first component and a second component or processing means for calculating the quantitative indicator wherein the calculation take as inputs the first component of the parameter for the first posture and the first component of the parameter for the second posture. Dekker discloses means for separating the parameter into a first component and a second component (para [0021] to [0022]) and processing means capable of processing means for calculating the quantitative indicator wherein the calculation take as inputs the first component of the parameter for the first posture and the first component of the parameter for the second posture (see para [0019], [0041] and [0052]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the means for detecting an arterial-blood-volume-dependent parameter disclosed by Rathgeber with the processing means and separating means disclosed by Dekker to automate the calculation disclosed by Rathgeber.

As to claim 18, Rathgeber discloses the first component is a pulsating component and the second component is non-pulsating component (see p 15 – $(PPI)=(AC/DC)$).

As to claim 19, Rathgeber discloses the indicator is dependent upon the ratio of the first component of the parameter for the first posture to the first component of the parameter for the second posture (Fig 6 and accompanying text – y-axis shows the ratio).

As to claim 20, Rathgeber discloses the indicator is directly proportional to the ratio of the first component of the parameter for the first posture to the first component

of the parameter for the second posture (see p 15 – $(PPI)=(AC/DC)$ and Fig 6 and accompanying text).

As to claim 21, Rathgeber discloses wherein the indicator is dependent upon the ratio of the second component of the parameter for the second posture to the second component of the parameter for the first posture (see p 15 – $(PPI)=(AC/DC)$ and Fig 6 and accompanying text).

As to claim 22, Rathgeber discloses wherein the indicator is directly proportional to the ratio of the second component of the parameter for the second posture to the second component of the parameter for the first posture (see p 15 – $(PPI)=(AC/DC)$ and Fig 6 and accompanying text).

As to claim 27, Rathgeber discloses measuring a parameter dependent upon the blood volume in a limb of the subject when the subject is in a first posture and also when the subject is in a second posture, different to the first posture (see section 2.2 on pp 14-15); and calculating a quantitative indicator wherein the calculation takes as inputs the first component of the parameter for the first posture and the first component of the parameter for the second posture (see p 15 – $(PPI)=(AC/DC)$ and Fig 6 and accompanying text), but does not disclose the step of separating the parameter into a first component and a second component. Dekker discloses the step of separating the parameter into a first component and a second component (para [0018]-[0019], [0022]). It would have been obvious to one of ordinary skill in art at the time the invention was made to combine the steps disclosed by Rathgeber with the parameter separating step

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disclosed by Dekker, since separating the pulsating and/or non-pulsating components allows arterial and/or venous flow and oxygen saturation to be independently monitored.

As to claim 28, Rathgeber discloses the first component is a pulsating component and the second component is non-pulsating component (see p 15 – $(PPI)=(AC/DC)$).

As to claim 29, Rathgeber discloses wherein the indicator is dependent upon the ratio of the first component of the parameter for the first posture to the first component of the parameter for the second posture (Fig 6 and accompanying text – y-axis shows the ratio).

As to claim 30, Rathgeber discloses measurement means operable to measure a parameter indicative of the blood volume of the subject's limb when the subject is in a first posture and to measure the parameter when the subject is in a second posture (see section 2.2 on pp 14-15). Rathgeber discloses a formula for calculating a quantitative indicator that is dependent upon the ratio of the parameter for the first posture to the variable value of the parameter measured for the second posture. (see p 15 – $(PPI)=(AC/DC)$ and Fig 6 and accompanying text), but does not explicitly disclose the processing means for determining it or the means for isolating a variable value of the measured parameter. Dekker discloses processing means for determining it or the means for isolating a variable value of the measured parameter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the means for detecting a arterial-blood-volume-dependent signal disclosed by

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Rathgeber with the processing means and separating means disclosed by Dekker to automate the calculation disclosed by Rathgeber.

As to claim 35, Rathgeber discloses measuring a parameter indicative of the blood volume of the subject's limb when the subject is in a first posture (see section 2.2 on pp 14-15); measuring the parameter indicative of the blood volume of the subject's limb when the subject is in a second posture (see section 2.2 on pp 14-15); determining a quantitative indicator that is dependent upon the ratio of the variable value of the parameter measured for the first posture to the variable value of the parameter measured for the second posture (see p 15 – $(PPI)=(AC/DC)$), but does not disclose the step of isolating a variable value of the measured parameter. Dekker discloses the step of isolating a variable value of a measured parameter (para [0021] to [0022]).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,542,421 A to Erdman shows a method and apparatus for cardiovascular diagnosis that also uses a change in posture.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Messersmith whose telephone number is (571) 270-7081. The examiner can normally be reached on Mon-Fri 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric Messersmith/
Examiner, Art Unit 3735
4/21/2011

/Miranda Le/
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